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October 18, 2007

VIA ELECTRONIC FILING

The Honorable Mary Pat Thyng
United States Magistrate Judge
United States District Court
844 King Street
Wilmington, DE 19801

Re: *Roquette Frères v. SPI Pharma, Inc., et al*, C.A. No. 06-540 (***)

Dear Judge Thyng:

We write in reply to SPI's letter of October 17, 2007, in which SPI asks for yet more time in which to provide its invalidity contentions. SPI has had more than ample time to describe the counterclaim which it raised almost a year ago, presumably after completing the requisite Rule 11 investigation.

SPI asserted its counterclaim of invalidity on November 6, 2006, alleging *in its entirety* that “[t]he claims of the ‘777 patent are invalid for failure to satisfy the conditions of patentability specified in Title 35, U.S.C. §§ 101, 102, 103 and 112.” (D.I. 15). Roquette served its interrogatories requesting SPI's invalidity contentions on April 5, 2007 – more than six months ago. For its part, Roquette has long since provided SPI with specific test results and corresponding documents that support its infringement claims.

SPI did not indicate in its Answer which paragraphs of the cited statutes it is relying upon for its counterclaim. However, SPI has since represented in its interrogatory response that it relies on prior art patents and, with respect to § 112, SPI informed the Court during the August 28, 2007 conference that it relies upon a contention that the claims are indefinite.

Specifically, SPI contends in its interrogatory response (Exhibit A hereto) that the patent-in-suit is invalid as “inoperable, anticipated, rendered obvious and/or indefinite, alone or in combination, by” a list of patents consisting of those which were cited on the face of the

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patent-in-suit and a few foreign counterparts. The depositions which SPI insists it needs before formulating its invalidity contentions have virtually no bearing on those contentions. No deposition testimony by any individual for Roquette could affect what the listed patents do or do not disclose. Moreover, if SPI asserted a counterclaim without any articulable basis it is in significant violation of Rule 11.

More particularly, SPI informed the Court during the August 28, 2007 conference that it alleged invalidity under 35 U.S.C. § 112 based upon *unspecified* claim terms which SPI considers indefinite. (Exhibit B hereto, at page 39, lines 12-21). SPI has yet to produce *any* information in support of that contention and depositions of Roquette's witnesses are irrelevant to what is necessarily an objective inquiry under 35 U.S.C. § 112, second paragraph.

Contrary to SPI's assertion in its letter, the Court did not hold that SPI must be allowed to depose "key witnesses," prior to the October 22 deadline. Indeed, SPI does not identify who it apparently now considers to be the *key* witnesses it requires. Whatever SPI's reason for considering some individuals to be key to its case, their depositions cannot be relevant to SPI's contentions of invalidity, which it represents are based on prior art or indefiniteness.

Moreover, any delay in the depositions of Roquette's witnesses was principally the result of SPI's own actions. For example, while Roquette served its deposition notices in May of this year, SPI postponed its notices until August. Despite Roquette's early notice, and after the Court had set the deadline for exchanging contentions, SPI proposed possible dates for its individual witnesses that extended well beyond the October 22, 2007 deadline. As for its Rule 30(b)(6) witnesses, SPI did not propose *any* confirmed available date until October 11, at which time it proposed dates later than the October 22 deadline.

Causing further delay, on September 11, again after the Court had set the deadline for exchanging contentions, SPI raised *for the first time* its demand that all Roquette individuals be deposed in the U.S. Even SPI's present letter to the Court was filed on the eve of the October 22 deadline, despite having scheduled the depositions of Roquette's witnesses more than three weeks ago. SPI should not be entitled to relief from its own tactics of delay.

Both Roquette and SPI have already conducted substantial discovery. Those parties have exchanged thousands of pages of documents, served and supplemented interrogatory responses, and have previously twice appeared before this Court in discovery dispute conferences. With the exception of SPI's Rule 30(b)(6) designee, all of the depositions contemplated when the Court set the October 22 deadline are confirmed and scheduled.

Accordingly, specific invalidity contentions are overdue. Additional relevant information, if any, that might be obtained through depositions should form a basis for supplementation of those contentions, not their creation.

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For all of the foregoing reasons, Roquette requests that the Court maintain its previously ordered deadline of October 22, 2007 for mutual exchange of the parties' contention interrogatory responses.

We believe that this matter can be decided on the papers. If, however, the Court wishes to schedule a conference on Friday, October 19, please be advised that Douglas Rigler will be at the New York office of Morgan Lewis that day for the previously scheduled deposition of SPI's marketing manager.

Respectfully,

/s/ Benjamin J. Schladweiler

Benjamin J. Schladweiler (#4601)

BJS/dam

Enclosures

cc: Dr. Peter Dalleo, Clerk (via efilng)
John W. Shaw (via email)
Oren D. Langer (via email)

1279696

EXHIBIT B

SHEET 1

1

1 IN THE UNITED STATES DISTRICT COURT
2 IN AND FOR THE DISTRICT OF DELAWARE
3 ROQUETTE FRÈRES, CIVIL ACTION
4 Plaintiff,
5 v.
6 SPI PHARMA, INC. and DRYTEC LTD., :
7 Defendants. : NO. 06-540 (MPT)
8 - - -

9 Wilmington, Delaware
10 Tuesday, August 28, 2007 at 5:00 p.m.
11 TELEPHONE CONFERENCE
12 - - -

13 BEFORE: HONORABLE MARY PAT THYNGE, Magistrate Judge
14 - - -

15 APPEARANCES:
16 - - -

17 MORRIS NICHOLS ARSH & TUNNELL
18 BY: BENJAMIN J. SCHLADWEILER, ESQ.
19 and

20 YOUNG & THOMPSON
21 BY: DOUGLAS V. RIGLER, ESQ., and
22 JEFFREY R. SNAY, ESQ.
23 (Arlington, Virginia)

24 Counsel for Plaintiff
25 - - -

YOUNG CONAWAY STARGATT & TAYLOR, LLP
BY: JEFFREY T. CASTELLANO, ESQ.

and

Brian P. Gaffigan
24 Registered Merit Reporter
25 - - -

SHEET 2

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1 APPEARANCES: (Continued)

2
 3 MORGAN LEWIS & BOCKIUS, LLP
 4 BY: DANIEL P. MURPHY, ESQ., and
 5 OREN D. LANGER, ESQ.
 6 (New York, New York)

7 Counsel for Defendants

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11 PROCEEDINGS

12 (REPORTER'S NOTE: The following telephone
 13 conference was held in chambers, beginning at 5:00 p.m.)

14 THE COURT: Good afternoon. This is Judge
 15 Thyng.

16 MR. SCHLADWEILER: Good afternoon, Your Honor.
 17 This is Ben Schladweiler from Morris Nichols representing
 18 Roquette; and with me on this call is Doug Rigler and Jeff
 19 Snay from Young & Thompson.

20 THE COURT: All right. Good afternoon,
 21 gentlemen.

22 MR. RIGLER: Good afternoon.

23 MR. CASTELLANO: This is Jeff Castellano.

24 THE COURT: I'm sorry. You got interrupted. I
 25 didn't hear the first name, sir.

1 I couldn't talk.

2 THE COURT: Oh, that's right. You had
 3 laryngitis. I forgot. It was very rough. All right.

4 MR. RIGLER: So let's see. We actually had a
 5 couple other things to talk to you about at the end of the
 6 conference which I think are not disputed but in terms of
 7 administration.

8 In terms of our complaints, we have only two.
 9 The first concerns other products. We need descriptions and
 10 sales information. They claim that we have accused only one
 11 product, which is the Mammogem EZ, and that is quite
 12 correct. However, we believe they are making associated
 13 products that are covered by the patent. Their comeback
 14 was, no, the patent discusses relatively pure mannitol.
 15 That is Claims 16, 18. Generally, the patent recites
 16 compositions which do include mannitol as an ingredient. In
 17 our letter, we showed you that we have good faith basis to
 18 believe that they're using this in other products.

19 THE COURT: Explain to me what your good faith
 20 basis is that they're using this in other products that
 21 would necessarily infringe your patent.

22 MR. RIGLER: The fact that they include
 23 mannitol. As you recall, there are two different types of
 24 the mannitol, and it looks to us as if either type is likely
 25 to infringe. It certainly, it seems to me, is within the

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1 MR. CASTELLANO: Oh. Jeff Castellano from Young
 2 Conaway from SPI Pharma; and here also on the line are
 3 Dan Murphy and Oren Langer from Morgan Lewis.

4 MR. MURPHY: Good afternoon, Your Honor.

5 MR. LANGER: Good afternoon.

6 THE COURT: Good afternoon, gentlemen.

7 I see that there are a number of what I will
 8 call mini-disputes among the parties. Why don't we address
 9 them? I recognize we have competing complaints by each side
 10 against the other and not that I read them in any particular
 11 order but I will start off with the plaintiff, what the
 12 plaintiff is complaining about that defendant has not
 13 produced and then let the defendant respond, see what we can
 14 get resolved there. And then I'll allow the defendant to do
 15 the same.

16 So who is going to speak on behalf of the
 17 plaintiff, Roquette?

18 MR. RIGLER: It's Doug Rigler. I'll probably
 19 take the lead, Your Honor.

20 THE COURT: You sound a lot better, Doug, than
 21 you did the last time.

22 MR. RIGLER: Thank you very much.

23 THE COURT: You had a cold I think the last
 24 time.

25 MR. RIGLER: I felt fine. I had laryngitis and

1 purview of information to which we're entitled. If they're
 2 right, then obviously we're not going to accuse the products
 3 but we have enough at least to know.

4 THE COURT: Well, let me put it this way, Doug.
 5 This is where I have some concern, the fact there has been
 6 no indication to me that you tested these other products to
 7 even determine whether or not they infringe. Your complaint
 8 was broader but you identified only one product that I
 9 understand that you felt infringed and that was the Mammogem
 10 EZ spray-dried mannitol; correct?

11 MR. RIGLER: That is correct. And there is a
 12 reason for that, and that is that we can't obtain these
 13 products. They are directed us to their website and that
 14 gives insufficient information. I would be perfectly happy
 15 to go out and purchase some commercially and test it and
 16 then let them know. I don't think that SPI lends itself to
 17 that. If they're willing to sell us some, fine. We can
 18 defer this whole discussion.

19 Are you willing to sell us 10 kilo lots of the
 20 other products?

21 MR. MURPHY: Your Honor, this is Dan Murphy from
 22 New York.

23 THE COURT: Yes, Dan.

24 MR. MURPHY: Roquette did make vague assertions
 25 of other products allegedly infringing their patent and the

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1 first time they actually specified a product that they
 2 believe might infringe was just recently in their August
 3 24th letter where they specifically finally referenced a
 4 Mannitol HS and a Mannitol HSE. So with respect to those
 5 products, they are not spray-dried mannitol products that
 6 are marketed by SPI Pharma, they are ingredients in a drug
 7 delivery system.

8 And Roquette might not have been aware but those
 9 products are combinations of mannitol and sorbitol which we
 10 believe puts them outside the range of the patent in suit
 11 because the patent in suit specifically discloses that the
 12 invention relates to relatively pure mannitol substances.
 13 So this is the first indication we've had from Roquette that
 14 they're interested in those particular mannitol ingredients
 15 which are co-processed mannitol-sorbitol formulations.

16 We prefer not to provide those samples to
 17 Roquette because they would fall outside the patent and we
 18 do not see the necessity, first of all, to provide discovery
 19 about them and now, at this point, to provide these samples
 20 just so they can confirm what we're telling them.

21 MR. RIGLER: In reply, I'd like to read to you
 22 claim 24.

23 "Compositions ..." exactly what Dan was
 24 talking about. "Compositions intended for the food and
 25 pharmaceutical fields, comprising the pulverulent mannitol,

1 we look back at the summary of the invention in the
 2 specification of the patent and the detailed description,
 3 it states expressly the present invention relates to a
 4 relatively pure pulverulent mannitol. And relatively pure
 5 is defined as meaning that at least 90 percent of the sugar
 6 or polyol content is going to be pure mannitol. So claim 1
 7 covers a mannitol, pulverulent mannitol with a richness of
 8 90 percent or greater, and our contention is that Mannitol
 9 HS and HSE products, as we have explained, are co-processed
 10 mannitol-sorbitol formulations in which the sorbitol content
 11 is greater than 10 percent.

12 MR. RIGLER: But that is the nub of the problem.
 13 I hear Dan saying that but we have no way of knowing. We
 14 can't obtain it publicly. We know it does contain the
 15 mannitol. We know that claim 24 covers the composition. It
 16 seems to me we're entitled to explore it.

17 MR. MURPHY: Well, Your Honor, I agree he is
 18 entitled to explore it and I think that is the purpose of
 19 depositions. When they are being held, Mr. Rigler can get
 20 sworn testimony from fact witnesses about this information.

21 THE COURT: Well, let me point out one of the
 22 arguments that you did make to me was the fact they hadn't
 23 tested any of these products so why should we be producing
 24 it? And they can just buy it commercially. What I found
 25 out, though, of the two products we're talking about, the

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1 according to claim 1, used as a sweetening agent, texturing
 2 agent, additive excipient or additive vehicle." It's
 3 plainly within claim 24 as he just described it and I think
 4 we're entitled to test it.

5 THE COURT: What does claim 1 say to me, Doug?
 6 Refresh my recollection because it's related back to claim
 7 1; right?

8 MR. RIGLER: That's correct. Claim 1 is the
 9 independent claim that claims the spray-dried mannitol and
 10 basically it's mannitol having friability within a certain
 11 range. I should tell you that I think seems to be the nub
 12 of the dispute right now. They claim that what they do is
 13 outside, we claim it's in, and, of course, that's for later
 14 down the line, but that's just by way of background. And
 15 then it defines the testing method for determining
 16 friability. Claim 1 then lists an apparent density for
 17 particle size and it also lists a rate of dissolution.

18 So it would be pulverulent mannitol. That means
 19 compressible. That's a long word and an unusual word but it
 20 basically means compressible mannitol with these particular
 21 characteristics, one of which at least is determined by the
 22 use of the specific test.

23 MR. MURPHY: Your Honor, claim 1, as Mr. Rigler
 24 stated, relates to pulverulent mannitol. The HS product is
 25 a combination of mannitol and sorbitol and claim 1 also, if

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1 Mannitol HS and the Mannitol HSE, I think is what you said,
 2 cannot be purchased commercially. At least, the Mannitol HS
 3 and the Mannitol HSE that you use cannot be purchased
 4 commercially. Is that correct?

5 MR. MURPHY: That is correct, Your Honor. But
 6 from the beginning, Roquette has been asking for other
 7 spray-dried mannitol products and those products containing
 8 mannitol are listed on the website and are publicly
 9 available. So we've told them consistently there aren't
 10 other spray-dried mannitol products that SPI Pharma makes.

11 THE COURT: Is Mannitol HS and Mannitol HSE
 12 something that SPI Pharma makes or puts together, or any of
 13 the defendants?

14 MR. MURPHY: It's manufactured by SPI Pharma,
 15 not the codefendants.

16 THE COURT: Okay. It would seem to me that
 17 although depositions would allow Mr. Rigler to test and find
 18 out information that the issue of testing is probably the
 19 final point. And I know what you represented. I'm not
 20 suggesting, Dan, that you are misrepresenting, but at the
 21 same time, I do think it's an area that can be explored and
 22 that should be produced. And how many? How much? What
 23 quantity did you need for testing, Doug? I didn't hear
 24 that.

25 MR. RIGLER: A small amount, 10 kilograms, and

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1 we'd be happy to pay for it.

2 THE COURT: So I think you need to produce and
3 allow them to at least test it.

4 MR. MURPHY: Okay, Your Honor.

5 THE COURT: Now, on other mannitol, though,
6 Doug, that you have expressed an interest in, if they're
7 commercially available, go buy them and test them.

8 MR. RIGLER: We would be glad to do that. And
9 again, I'm not quarreling with Dan but it's my information
10 that notwithstanding it being listed on the web, it's
11 basically in order form. And if we go back and say "we're
12 Roquette and we'd like to buy some," we'll be turned out.
13 And if we can get, we will. We'll try to work it out.

14 THE COURT: And I think you should try to work
15 it before you start asking for production of other
16 information because it may turn out these products are not
17 relevant to this lawsuit.

18 MR. RIGLER: And obviously I think it goes
19 without saying that we don't want to waste our time, their
20 time or the Court's time on products that fall outside the
21 claims if we don't have some reasonable basis for thinking
22 they're in.

23 THE COURT: And I think the best way is really
24 finding out by testing it and confirming it before we start
25 going into other types of information and data and have them

1 certainty but I think they're entitled to more and my
2 proposition to them had been let's not play games. I had
3 proposed by today to have exchanged -- or tomorrow to have
4 exchanged their answers to our infringement interrogatories
5 and we'll give them claim charts which will amplify the
6 information we have already given them, but I think this is
7 very important to move the case along. There is just no
8 reason for delay on this. None.

9 THE COURT: All right. On the issue of
10 your failure to respond or provide adequate information
11 concerning the contention interrogatories, Dan, are you
12 going to be addressing that point on behalf of SPI and the
13 defendants?

14 MR. MURPHY: Yes, Your Honor.

15 THE COURT: I think it's interesting, I don't
16 think anybody gave me a copy of the answers to the interrogatories
17 to show me where the deficiency is except I did get
18 a bunch of letters telling me what the deficiency is or
19 trying to do what you argued back and forth with the other
20 concerning the deficiency but go ahead.

21 MR. MURPHY: Yes, Your Honor. We did provide
22 specific prior art pieces that we allege are part of our
23 invalidity contentions. We agree that they're entitled
24 to our invalidity contentions and we will supplement our
25 contentions as appropriate but we disagree with Mr. Rigler

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1 go through that labor and have you go through the labor of
2 reviewing it.

3 MR. RIGLER: Okay.

4 THE COURT: What is your other point?

5 MR. RIGLER: Our other point is we need their
6 invalidity contentions. We have none. The case was filed
7 last year, as you're aware. We lost Judge Jordan. There
8 have been delays, but according to the present schedule,
9 which I would like to revisit with you, expert reports are
10 due in a month and actually I think a day under a month and
11 we have no invalidity contentions and we've been unable to
12 obtain any information and it's well past due.

13 I just can't imagine, 10 months into the case,
14 why they won't give us. If they're raising invalidity as
15 their principal defense, a co-principal defense, they had
16 to tell us and the time has long since past. And an
17 argument that, "gee, we're lagging on discovery," that's not
18 true. We've exchanged. We've exchanged documents. We've
19 answered interrogatories. We've had some discussions and
20 supplemental answers. We're pretty far down the line. It's
21 time to come to the party.

22 While I talk about "coming to the party," one
23 of their complaints is they want more information on our
24 infringement claims. We contend that we identified the
25 particular claims and particular products of which we have

1 that this case is far along. The fact is we haven't even
2 had a single fact deposition.

3 THE COURT: I was wondering about that. That
4 was my next question as to whether or not, beyond the paper
5 discovery, the parties have taken any depositions.

6 MR. MURPHY: We have not, Your Honor. And the
7 paper discovery has been limited, as we showed in our
8 opening letter.

9 THE COURT: Let me do this. I know Mr. Rigler
10 kind of jumped the gun on that. I really do want to
11 address SPI's invalidity contentions and, quite frankly, the
12 contentions by both parties for which they bear the burden
13 of proof.

14 I'm kind of operating in the dark a little bit
15 as to how they were inadequate. Although I know it's
16 expressed in letters, it's just kind of going at each other
17 back and forth by, to some degree, predominantly conclusory
18 statements which makes it very, very difficult for me to
19 analyze whether the answers have been adequate. I recognize
20 that this Court does encourage contention interrogatories to
21 be answered earlier in the game and each party is expected
22 to answer them with the information they presently have.
23 And they have the obligation, affirmative obligation under
24 Rule 26(e) to update them and supplement them on a regular
25 basis.

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1 Beyond the Court sitting there and checking in
 2 with you every month to find out if that supplementation
 3 has occurred on some type of regular basis, which is not
 4 something I particularly care to do, nor would I think you
 5 want me to do, I don't know how to address those types of
 6 issues adequately when I've got the information that I have
 7 in front of me. So it's problematic. I mean I am hearing
 8 from both of you each side didn't do enough. I don't know
 9 why you think that necessarily -- I know to some degree --
 10 and how they hadn't done enough. And so it does make it
 11 complicated and difficult for the Court to sit there and
 12 say you're wrong, they're right, do it. It's difficult
 13 to go beyond telling you to do it and to do regular
 14 supplementation.

15 Now, one of the things I think that you offered,
 16 Doug, from your aspect for infringement was to provide a
 17 claim chart. Were you looking for something in exchange for
 18 that?

19 MR. RIGLER: We have an obligation and we're
 20 willing to do that. We do think we answered their
 21 interrogatory and provided the information but as you just
 22 pointed out, that gets into a game of "who struck John."

23 THE COURT: Yes.

24 MR. RIGLER: And I guess my point is why don't
 25 we just have a date and exchange the full amount of

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1 MR. RIGLER: If we knew your contentions, that's
 2 fine. And we are not resisting depositions. That takes us
 3 a little afield, but let's get the contentions out there and
 4 know what we're arguing about.

5 With respect to depositions, that is a little
 6 off subject but I'm happy to discuss it. We noticed
 7 depositions in May, and we gave them dates certain in June,
 8 so they had plenty of time. But we pointed out that the
 9 content and the efficiency of those depositions would be
 10 strongly influenced by whether or not the Drytec parties are
 11 defendants. And I think they agreed.

12 THE COURT: So you need that information. You
 13 need a decision from the Court is what you are saying?

14 MR. RIGLER: Yes, exactly. And I think they
 15 agreed with that. And then, as you know, we added the
 16 Drytec defendants and you permitted us to amend and now we
 17 took the discovery you permitted and the motion is pending
 18 before you.

19 THE COURT: And the motion was completed when,
 20 counsel? Because we had the motion. Then I said, in light
 21 of what else was going on, let's get it all in one fell
 22 swoop rather than piecemeal.

23 MR. RIGLER: Exactly, and that is what we did.
 24 That is now before you.

25 THE COURT: When was the motion completed? Does

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1 information. Something I think you should be aware of is
 2 that their invalidity contentions were made under 102, 103,
 3 101 and 112. In other words, they throw the book at us and
 4 all we've seen, literally, is the references that were cited
 5 in the patent, itself. And I agree you don't know what went
 6 back and forth but when I tell you that, I think you can
 7 see that we have nothing. And with this vast array of
 8 generalized infringement contentions and nothing specific,
 9 it's just well past time.

10 I'm certainly willing to step up to the plate
 11 and enhance the information. We did give them responsive
 12 information but I think they're entitled to more from us. I
 13 agree with you that one isn't necessarily a captive of the
 14 other, but let's just get it going. Let's get the case
 15 moving, so why don't we agree on a date to exchange these?

16 THE COURT: You can answer that, Dan.

17 MR. MURPHY: I agree. We can get the case going
 18 and we should agree on a date certain to exchange the
 19 contentions. But from our perspective, I think we need to
 20 take a few depositions at least. I think that is fair
 21 considering that we have limited paper production and no
 22 depositions have been taken yet. I think it's fair that
 23 we be given a chance to explore some of these issues at
 24 deposition with their witnesses and then supplement our
 25 responses and give further contention responses.

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1 anybody recall when the briefing was done?

2 MR. RIGLER: I think in July. I'm not sure.

3 MR. MURPHY: I think the last week in July was
 4 when the last paper was submitted.

5 THE COURT: Okay.

6 MR. RIGLER: But in the meantime, they came back
 7 in August with a deposition list of their own. And that's
 8 fine, we don't resist depositions, but that is not an excuse
 9 for deferring on the contentions.

10 THE COURT: Well, I point out to you, counsel,
 11 that (A) when a lawsuit is brought and (B) when an
 12 affirmative responses are made, there is an expectation that
 13 everybody will abide by Rule 11 and be alleging, be making
 14 representations either in their complaint or answer that is
 15 supported by some basis. These are not just pulled out of
 16 thin air. That there was a basis for doing that and there
 17 is the reason why. And I think one thing I found in a lot
 18 of these cases is the reason why they're often lacking to a
 19 large extent -- and to that extent, I am somewhat concerned
 20 about. I'm not suggesting the parties have done that. What
 21 I'm suggesting is that there is this back and forth and not
 22 getting off first base.

23 Are the two of you saying to me that without the
 24 Court's decision on the dismissal for lack of jurisdiction
 25 over the person filed by the Drytec entities, various

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1 entities that you can't start worthwhile deposition
2 discovery?

3 MR. RIGLER: That's correct. We would be back
4 for round two. We've agreed on a limit on the number of
5 hours and it just would be very inefficient I think all the
6 way around.

7 MR. MURPHY: Your Honor, this is Dan Murphy.
8 When we spoke with Mr. Rigler, we did agree that we would
9 be willing to put off depositions until we received your
10 decision on the motion to dismiss, but the case can go
11 forward and depositions can go forward without that
12 decision. It's obviously your discretion and we're amenable
13 to either decision but we do think we don't agree that the
14 case has to hinge on going forward on the resolution of that
15 motion.

16 THE COURT: Is the concern, Doug, that you made
17 that these people may have to be re-deposed?

18 MR. RIGLER: Yes, it is, or even the scope of
19 the deposition. You recall that the Drytec people are in
20 this because SPI has been doing what they call toll
21 manufacturing of an infringing product.

22 THE COURT: Yes.

23 MR. RIGLER: They also were making components
24 for the machinery and then shipping that into the United
25 States, but let's concentrate on the product. They're

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1 If the Drytec defendants, either one or all of
2 them, are no longer in the case, can discovery be obtained
3 from them, third-party discovery be obtained from them or
4 are they all foreign entities and you can't do that, you'd
5 have to go through Hague Convention and go through that
6 exercise?

7 MR. MURPHY: Your Honor, they are foreign
8 entities.

9 MR. RIGLER: SPI is representing both of them.
10 I suppose they could agree. I was waiting to hear Dan's
11 answer. It would be very difficult. As a practical matter,
12 we would not be getting that discovery from Drytec.
13 Theoretically, there are ways you could get some discovery
14 but I think you can understand the delay and the dilemmas
15 on that.

16 THE COURT: Yes.

17 MR. MURPHY: Your Honor, can I just note that we
18 disagree with Mr. Rigler in the sense that, of course, we
19 can take fact depositions of his witnesses and that does not
20 involve your decision related to the Drytec entities. So
21 we could go forward, SPI can, and take those depositions,
22 which would give us further information and let us
23 supplement our contention responses. So I don't see the
24 connection between. If he desires to delay, that's one
25 thing, but ...

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1 making the product, they're testing the product. I think
2 it's fair to say that they tried to design around the patent
3 on the friability and we contend they failed. They contend
4 they succeeded. That is going to be a very important issue
5 at trial.

6 If we don't have quality testing to know what
7 they did in Drytec, that influences, I would say, perhaps
8 the most major influence, the most influential point in the
9 case. And we'll abide by your decision, of course, but if
10 we have discovery over what Drytec did before they sent this
11 stuff -- they sent some of it to Delaware where it was
12 further tested and maybe we can get SPI's test results on
13 that, but they sent a lot just directly into commercial, for
14 commercial use. And we don't know what their test results
15 were. We know that there is a wide range of friability
16 results. We need that information. And so it's sort of
17 crucial to the case.

18 THE COURT: Well, technically, are they not in
19 the case right now, absent the motion to dismiss?

20 MR. RIGLER: Technically they're in the case
21 unless their motion is granted, I would say.

22 THE COURT: Okay. So that my ruling before of
23 allowing discovery on Drytec -- but let me back up a little
24 bit. Let's assume this for purposes of the discussion right
25 now.

1 THE COURT: Well, can't he also take the
2 deposition or can he take the deposition of SPI Pharma
3 people?

4 MR. RIGLER: We could proceed with that, I
5 suppose. I don't know if we would have to come back for
6 round two but ...

7 THE COURT: And you may have to, to supplement
8 it.

9 MR. RIGLER: I may have to, but to the extent
10 that we can avoid it ...

11 THE COURT: Well, what my concern is, Doug, in
12 light of the fact that briefing on this got completed, I
13 think, from what I checked, was the last brief that was
14 filed, was on August 3rd and we're now at August 28th. And
15 I assure counsel that in the last 25 days I've been doing
16 a heck of a lot of stuff. Okay? So it's not that I'm
17 intentionally ignoring your concerns here. At the same
18 time, I haven't read the briefs and I haven't looked them
19 over yet but we'll put them on a higher list to try to get
20 them addressed sooner rather than later, but it would seem
21 to me there can be some form of discovery taken at least at
22 this point, including maybe some document information that
23 Drytec may very well -- and I recognize this is a problem
24 because I limited the depositions to finding out the
25 information concerning jurisdiction, but there has got to

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1 be document information that Drytec may have such as test
 2 results because it seems to me -- I'm not suggesting to sit
 3 down and take depositions but it would seem to me that this
 4 is the type of information that SPI Pharma may have the
 5 right to ask and even obtain; is that correct?

6 MR. MURPHY: Your Honor?

7 THE COURT: Yes.

8 MR. MURPHY: I'm sorry. I missed your last
 9 question.

10 THE COURT: I'm sorry. Would SPI Pharma have
 11 the right to ask the Drytec entities for testing information
 12 and things like that, things along those lines?

13 MR. MURPHY: Your Honor, Oren Langer is going to
 14 address that.

15 THE COURT: Thank you.

16 MR. LANGER: Your Honor, this is Oren Langer.
 17 The way that the manufacturing at Drytec worked was that
 18 Drytec was a toll manufacturer and SPI ran the show in terms
 19 of testing and the instructions on what to do with the
 20 product as it was being made.

21 THE COURT: Okay.

22 MR. LANGER: All of the testing, which we refer
 23 to as in-process testing, has all been produced already to
 24 Roquette, and that entails all of sample testing and testing
 25 of the commercial product. All that documentation has

24

1 patent. That is what I'm drawing from it or am I wrong on
 2 that, Doug?

3 MR. RIGLER: This is Doug again. I think that
 4 is incorrect.

5 THE COURT: Okay. Thank you.

6 MR. RIGLER: I am aware, as Oren said, that we
 7 do have some quality tests. Part of our argument on
 8 jurisdiction is that they were shipping it into Delaware to
 9 SPI which tested it there, giving approval for the further
 10 shipments. But I guess I disagree fairly strongly with Oren
 11 that we have the complete records because it's my impression
 12 they have deposited Mr. Kennett twice now, I think. And I
 13 have seen a limited number of documents, very limited, but
 14 it's my impression they were doing batch testing. They
 15 weren't just sending everything over to Delaware. So,
 16 sure -- not sure but I think that we have a fairly complete
 17 set of the quality tests on the quantities sent to Delaware,
 18 but a lot of it was sent to Grand Haven, Michigan is my
 19 understanding for processing or maybe making into these
 20 compositions. And I don't think we have the batch testing
 21 as Drytec performed that.

22 MR. LANGER: Your Honor, this is Oren. Well,
 23 again, these are points of contention. I don't want to get
 24 into the substance of our motion because that is not what
 25 the hearing is about.

23

1 already been produced.

2 THE COURT: Okay. Wait a minute. I'm just
 3 trying to find out something. Let me get this down, Doug,
 4 and then you can talk, okay?

5 So you are saying that there would have been an
 6 obligation on the part of the Drytec entity or entities to
 7 provide you with this testing while they were making the
 8 product; for quality control issues, I would guess.

9 MR. LANGER: Actually, it was the SPI entity
 10 that conducted the testing.

11 THE COURT: Oh, they actually did the testing?

12 MR. LANGER: Correct.

13 THE COURT: Drytec didn't do the testing?

14 MR. LANGER: Correct. Drytec provided the
 15 facilities for the manufacturing to take place, but all the
 16 in-process testing, the quality control testing as you
 17 reference it, was carried out by SPI and all that
 18 information has been produced and we have given Roquette
 19 the Bates numbers for all that information as well.

20 THE COURT: Now, Doug did reference other
 21 testing that Drytec may have done or products that may have
 22 come to the United States to other entities. I guess he is
 23 saying, suggesting that Drytec may have manufactured and had
 24 tolling arrangements with other entities and these products
 25 ended up in the United States that allegedly infringe the

24

1 THE COURT: Sure.

2 MR. LANGER: But I can represent that SPI Pharma
 3 did conduct quality control testing of its product that was
 4 being toll manufactured by Drytec. And all of those tests,
 5 what we refer to as in-process testing, are all produced,
 6 have all been produced.

7 THE COURT: Now, did you require batch testing
 8 being done by Drytec for any of this products that they were
 9 making for you?

10 MR. LANGER: Again, Drytec didn't conduct any
 11 of the batch testing, and all of the batch records have
 12 all been produced for all of the products, and those are
 13 products that are sold out of Grand Haven. And all the
 14 in-process testing, the testing that is conducted during the
 15 course of the manufacture have all been produced as well.
 16 And I imagine that Mr. Rigler is referencing this testing
 17 based on documents that he has received that refer to them.

18 THE COURT: Well, I think he is also referencing
 19 this information in part from a deposition that he did take
 20 where he has some concerns I think based on that deposition.
 21 You tell me if I'm wrong, Doug, that you don't have all the
 22 testing for some reason. For some reason, you believe you
 23 don't have all the testing. And I don't know why.

24 MR. LANGER: Let me also just add one more point
 25 for the Court to understand when we've provided Drytec

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1 documentation prior to both Kennett depositions and during
 2 the course of the second Kennett deposition, Mr. Rigler
 3 asked for even further documentation which we asked the
 4 witness to look for. He found them and we also produced
 5 those. So there is Drytec documentation that has been
 6 produced, and we've even followed up with Mr. Kennett and
 7 we produced those documents as well. And to this point,
 8 that is the extent of it.

9 MR. RIGLER: Those document requests were not
 10 directed to liability issues. Judge Thynge was quite
 11 definite in limiting us to jurisdictional questions and the
 12 documents we received and the requests for supplementation
 13 that we thought we were entitled to concerned jurisdictional
 14 issues, not liability issues such as the actual friability
 15 of the various batches.

16 THE COURT: Can you, counsel on behalf of the
 17 defendants, represent that the testing that was produced
 18 covered everything?

19 MR. LANGER: We can represent that all the
 20 in-process testing that took place for the production of the
 21 Mammogem EZ product has been all been produced and that
 22 every batch record for every batch produced and sold of the
 23 Mammogem EZ product has been produced. I believe that is as
 24 of May of 2000. I'm not entirely sure of that point, and I
 25 would have to go back and check to get really just the

1 just said, but again I can just make the statement and
 2 represent that all of the batch data has been produced, has
 3 been identified to Roquette as well as all of the in-process
 4 testing.

5 THE COURT: Whether it was tested in England or
 6 the United States.

7 MR. LANGER: Correct, all of the in-process
 8 testing has been done. Again, I don't want to get into the
 9 motion for jurisdiction.

10 THE COURT: Oh, I understand that.

11 MR. LANGER: But, again, all the in-process
 12 testing and all of the batch records have been produced.

13 THE COURT: And again confirming you didn't
 14 look at it from the standpoint of limiting it when you did
 15 this production on jurisdictional issues but just produced
 16 everything in the testing arena that was requested or, I
 17 should say, in the testing arena without the limitation of
 18 saying this goes to jurisdiction, this is all we have to
 19 produce rather than this goes more to liability and we're
 20 not producing that.

21 MR. LANGER: That's correct. We asked SPI
 22 without any limitation to give us all of the batch records
 23 and all of the in-process testing and that's what we
 24 produced to Roquette.

25 MR. RIGLER: Yes, but did you ask Drytec to do

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1 recent productions, if any have been made. But in terms of
 2 this litigation and in terms of from Day One of when the
 3 product was sold commercially, all of the batch information
 4 and all of the in-process testing has been produced.

5 THE COURT: And that was not limited to a
 6 jurisdictional issue but also would have covered -- you're
 7 representing to me that you didn't limit your search just to
 8 concentrating on the jurisdictional issue?

9 MR. LANGER: That's right, Your Honor, because
 10 SPI Pharma was the one that conducted all of that testing.

11 MR. RIGLER: In England, Oren?

12 MR. LANGER: No, in the United States.

13 MR. RIGLER: But the batch.

14 MR. LANGER: The batch records may have come
 15 from -- may have been -- I'm just trying to think. The
 16 in-process testing was not conducted in England and I'd have
 17 to go check on the batch records. Either way, it's all been
 18 produced.

19 MR. RIGLER: But if it was in process, if
 20 the process was done in England, performed in England and
 21 the material was changing then and then they sent some
 22 quantities over to Delaware for SPI to test for quality
 23 assurance or whatever, that's not going to get the batch
 24 testing.

25 MR. LANGER: I'm a little unclear as to what you

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1 that?

2 MR. LANGER: I did not ask Drytec to do that
 3 because Drytec was a toll manufacturer and did not do that.

4 THE COURT: You are representing that Drytec did
 5 not do any testing?

6 MR. LANGER: I would have to go back and check
 7 because I haven't looked at that information recently. The
 8 only thing I can represent is, with respect to SPI Pharma
 9 and the batch records, for every batch of Mammogem EZ sold
 10 in the United States and all the in-process testing since
 11 the initial production, the initial commercial production of
 12 Mammogem EZ.

13 MR. RIGLER: Jeff Snay, my colleague, just wrote
 14 me a note indicating that his review of the documents was
 15 that in-process testing documents was signed by the Drytec
 16 personnel. Jeff is looking for that now but it seems to me
 17 that indicates testing was being performed.

18 Okay. What do we have there? Ah. This was
 19 produced by SPI, SPI1227, but it's a Drytec lab test result
 20 record.

21 MR. LANGER: Right, and it does bear an SPI
 22 number. It was produced by SPI.

23 THE COURT: Okay. That still doesn't answer the
 24 question whether Drytec was doing any testing for SPI, does
 25 it?

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1 MR. RIGLER: Yes.

2 MR. LANGER: Right.

3 THE COURT: Well, that's the question, I'm
4 sorry, I'm directing to SPI's counsel. What it doesn't tell
5 me, Oren, what I'm not certain about is whether Drytec was
6 doing testing for SPI and that SPI would have received all
7 of the documents from Drytec regarding the testing. Am I
8 correct on that?9 MR. LANGER: Well, for the commercial batches
10 that are sold, again, I'm talking about commercial batches,
11 I have to go back and check on the trial batches and the
12 things of that nature, but it's my understanding that SPI
13 Pharma tested. The batch records all came out of SPI
14 Pharma, but ...15 THE COURT: It would seem to me, counsel, that
16 you do have areas of discovery for depositions that you can
17 take certainly for SPI Pharma to confirm this particular
18 issue, whether they were doing all the testing or whether
19 they're relying upon testing being done by Drytec or whether
20 they were actually physically doing all the testing. So
21 there are areas. I think that both plaintiff and defendant,
22 that is, defendant SPI Pharma, can start depositions so both
23 of you can move forward and get a game plan laid and then
24 deal with the Drytec depositions if they ever occur.

25 But as counsel pointed out to me, you probably

1 MR. RIGLER: I don't think she was saying that
2 at all. She was saying she thinks there is a basis why
3 depositions should move forward but there is just no reason
4 at all to delay. I don't get "hide the ball." It makes no
5 sense to the context of the case when we're this deeply into
6 the case.7 THE COURT: Let me suggest this: How soon do
8 you think you are going to start taking depositions? How
9 soon do you think they're going to be scheduled, counsel?10 MR. RIGLER: I have a little priority first but
11 I can start around the 1st of October. I'll be out of the
12 country mid September. Otherwise, I'd start earlier.13 MR. MURPHY: We had noticed for the end of
14 September but we expected October as well.15 MR. LANGER: Your Honor, this is Oren.
16 Mr. Rigler notified us, though, that the witnesses were
17 all I believe French nationals, wouldn't be available in
18 September so I would imagine we would also be getting
19 started in October.20 THE COURT: And realistically, gentlemen,
21 roughly how many depositions do you think you are going to
22 be able to get started, maybe not completed because of this
23 issue concerning Drytec; but hopefully by that time before
24 you start the depositions, maybe you actually will have an
25 opinion from me; but how soon or how many depositions do you31
1 need an answer from this Court sooner than later concerning
2 the jurisdictional issue and I will get that teed up as soon
3 as possible. And it may be I read through things and bring
4 you on the phone and tell you what my decision is rather
5 than waiting to write that beautiful prose that can come out
6 of this chambers on occasion.

7 MR. RIGLER: Okay.

8 THE COURT: That might be the better way to go.
9 So I have something to potentially read over the Labor Day
10 holiday. Thank you.

11 (Laughter.)

12 MR. RIGLER: What can we say?

13 THE COURT: No, I'm only kidding, counsel.

14 MR. RIGLER: I know.

15 THE COURT: I wish it could be by osmosis where
16 I lay my hands on it and the knowledge goes up to the brain,
17 but unfortunately that doesn't happen. I haven't figured
18 that out yet.19 MR. RIGLER: May I suggest we set a date to do
20 the contention stuff and then move forward? I take your
21 message on the depositions; and I thank you, and Oren does,
22 too; but can we get an exchange date for the contentions?
23 Dan, Oren? A week? What do you want?24 MR. MURPHY: Doug, I thought the judge was
25 saying we should get depositions under our belt before.33
1 think you will be taking in that time period, at least
2 covering the plaintiff and SPI Pharma?3 MR. RIGLER: I suspect that we will start out
4 with three or four depositions, I think. I'm quite certain
5 there is a limit on the number of hours of depositions.

6 THE COURT: And I will --

7 MR. RIGLER: So I think we can move forward.
8 Yes, 45 hours.9 THE COURT: Well, understand, I'm not talking
10 about the limit of the hours right now, Doug.11 MR. RIGLER: We can start with, say, three
12 witnesses in early October.13 THE COURT: Okay. And how many witnesses do you
14 think, Dan, you are going to be starting off with in around
15 the same time frame?

16 MR. MURPHY: Four witnesses, Your Honor.

17 THE COURT: Okay. So that is seven witnesses
18 that could probably be deposed by roughly mid October or so.

19 MR. MURPHY: Right, Your Honor.

20 THE COURT: So I do think that having some
21 depositions might be appropriate, Doug. I understand your
22 concern about hiding ball and that issue but I do think that
23 by the end of October, the parties can be doing substantial
24 exchange and getting these contention interrogatories,
25 getting these contention matters down and producing either

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1 more documents or further information explaining it.

2 Now, I do not have the schedule in front of me.
 3 I have no idea what your schedule looks like right now. It
 4 may be that the schedule that we presently have entered is
 5 going to be -- let me just see. Do you have a cutoff date
 6 for discovery?

7 MR. RIGLER: We do. It's December 21, and I
 8 think that is unrealistic.

9 THE COURT: Yes, I think it is, too,
 10 particularly when you are going to have expert testimony due
 11 on September 28th.

12 MR. RIGLER: What I was going to suggest, we
 13 discuss it preliminarily during our meet and confer. I
 14 think both parties agree that the schedule is going to be
 15 bumped. I would suggest bumping it 120 days. I don't think
 16 that hurts anything. We don't have a judge -- a trial
 17 judge.

18 THE COURT: Yes, I understand. I understand
 19 that you didn't mean that pejoratively.

20 (Laughter.)

21 THE COURT: What I suggest, counsel, why don't
 22 you work that out, for 3c, which is the discovery cutoff,
 23 3d, what your proposals are. Probably we should have
 24 another interim status report and that, in some ways, is
 25 going to be dictated by -- why don't you give me suggested

1 better idea.

2 MR. RIGLER: We would be glad to do that. And
 3 we will do that. The June conference was cancelled.

4 THE COURT: Thank you.

5 MR. RIGLER: This is one of those things that
 6 happened during the discussion about amending the complaint.

7 THE COURT: Yes.

8 MR. RIGLER: And my recollection is that you
 9 were hesitant to, you thought maybe it didn't make sense to
 10 build dates into a schedule when we didn't know who the
 11 judge would be or basically to put in claim construction
 12 dates for someone who hadn't even been appointed.

13 THE COURT: Well, understand what I'm saying,
 14 Doug, is I'm not talking about the hearing on claim
 15 construction, nor am I talking about the date for the
 16 tutorial.

17 MR. RIGLER: Oh, okay.

18 THE COURT: Because as I said paragraph 9,
 19 paragraphs 13 and 15 through 17 really affect the Court but
 20 the other paragraphs in the scheduling order more affect
 21 the parties and those paragraphs I don't mind necessarily
 22 completing. I've had them completed in other cases. You
 23 know, it's sort of a rock-and-a-hard-place situation is what
 24 I'm saying. You could end up having all this done and then
 25 just sitting and waiting for the rest of it.

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1 dates or suggested time frame that you would want another
 2 interim status report, recognizing that it's roughly about a
 3 week to 10 days between the interim status report and the
 4 status conference. I don't like to do it much longer than
 5 that.

6 And the question I have, too, is we haven't got
 7 claim construction issue identification or case dispositive
 8 motions or any of those matters -- they were all supposed to
 9 be discussed during the June 26th conference and right now
 10 I can't remember what we discussed during the June 26th
 11 conference -- and the tutorial and matters such as that. I
 12 recognize that the tutorial probably and the hearing on
 13 claim construction; the tutorial, that is paragraph 9 and
 14 paragraph 13, paragraphs 15 through 17; is probably more
 15 geared for the trial judge and along those lines, and
 16 claim construction issue identification. We don't have
 17 any of those dates in, and the claim construction issue
 18 identification is something that directly affects counsel,
 19 directly affects the parties, and the claim construction
 20 briefing on claim construction directly affects the parties
 21 as well, and case dispositive motions.

22 So those are things that probably also should
 23 be discussed and maybe we should start considering about
 24 building it into the scheduling order, particularly if you
 25 are going to extend the discovery date, and then you get a

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 1 But I've found that other parties have expressed
 2 a desire to have those dates included, so I throw that
 3 option out to you so that there is, for example, I think
 4 under paragraph 11, claim construction issue identification
 5 is probably going to be more helpful to you and it's one of
 6 the issues that is related to contention interrogatories and
 7 that may be something that helps the both of you to get this
 8 case on track. It also helps the both of you to tee this
 9 case up if there is any possibility for some type of
 10 mediation or settlement discussions.

11 But you are right, the paragraphs 9, 13 and, as
 12 I said, 15 through 17 really more involves the Court. The
 13 other paragraphs involve you, involve the parties. So I
 14 throw that out as a possibility that they may be areas that
 15 you want to start putting in some dates now with the hope
 16 that if we, by some miracle, get a judge in the near
 17 future -- and all of us I think were hopeful a couple
 18 weeks ago when one of the candidates submitted to the
 19 President was reported as being subject to the background
 20 investigation by the FBI and the IRS, but then that was
 21 quoted in the paper over a week and we haven't heard
 22 anything since and I have no further information as to what
 23 is happening in this regard.

24 But I throw that out as a possibility. And
 25 certainly the other dates that we already have in here, to

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1 the extent you want to change them, fine. And then just get
 2 that to me. And I just look forward to what your proposal
 3 is and then we'll either modify it or sign-off on it.

4 You said that in mid September, Doug, that you
 5 were going to be unavailable? When does that start?

6 MR. RIGLER: That's correct.

7 THE COURT: When does that start in mid
 8 September?

9 MR. RIGLER: It starts in September. I'm going
 10 to be away over Labor Day but then September 12th through
 11 September 25th, I'm out of the country.

12 THE COURT: All right. Then by September
 13 10th -- I think that is a regular workday. Yes, it's a
 14 Monday.

15 MR. RIGLER: Yes, we can do that.

16 THE COURT: The parties could probably get that
 17 or counsel could get that to me.

18 MR. RIGLER: Sure.

19 THE COURT: And I could address it then. And I
 20 will start working. I recognize you are going to be away,
 21 and I will attempt to start working on the motion. And as I
 22 said, it will either be something written to you or getting
 23 you on the phone and just explaining to you what my decision
 24 is and why and just doing it briefly.

25 MR. RIGLER: Okay. Can we get some preliminary?

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1 that supplementation then. And I thought by then that that
 2 should be substantial in light of the fact that you have had
 3 document exchange, albeit as it may, and you also had
 4 depositions taken. So I really do think by towards the end
 5 of October that should be done. And I don't have a calendar
 6 in front of me right now, counsel, but what is the Monday in
 7 the last week of October, please?

8 (Unidentified Speaker): The 29th, Your Honor.

9 MR. RIGLER: The 29th.

10 THE COURT: I think you could probably get it
 11 done before the 29th.

12 MR. MURPHY: Yes, Your Honor. We will.

13 THE COURT: I think by the 22nd would be
 14 appropriate.

15 MR. RIGLER: We missed that. Sorry.

16 THE COURT: The 22nd, which is the Monday
 17 before.

18 MR. RIGLER: Okay.

19 THE COURT: More developed, much more complete
 20 answers than what have been provided previously.

21 MR. RIGLER: Okay.

22 MR. MURPHY: Yes, Your Honor.

23 THE COURT: All right? Is there anything else
 24 that we need to address at this time, counsel?

25 MR. MURPHY: Of course, SPI has its affirmative

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1 Can we get initial answers to the contention
 2 interrogatories?

3 MR. MURPHY: We've already provided that,
 4 Mr. Rigler.

5 MR. RIGLER: The only answer was to list, as I
 6 said, the patents that were listed in the application
 7 itself. And that is just insufficient.

8 THE COURT: Well, let me ask you, Dan, my
 9 understanding is your defenses to the patent were not just
 10 limited to prior art; correct?

11 MR. MURPHY: That's right, Your Honor.

12 THE COURT: Do you have any other basis as to
 13 why you brought the other defenses against the patent and
 14 raised them in your answer? You obviously did. Otherwise,
 15 you've got Rule 11 concerns.

16 MR. MURPHY: Yes, Your Honor. I mean we raised
 17 the 112 defense and we will allege indefiniteness, some of
 18 the terms in the claims. And we haven't specified which
 19 claim terms are indefinite but we had a reasonable basis for
 20 alleging a 112 invalidity contention and we will make that
 21 plain when we serve our supplementation.

22 MR. RIGLER: That is the point. Let's have a
 23 date.

24 THE COURT: Well, I suggested or I put out
 25 there, Doug, that you do it by the end of October and do

1 requests.

2 THE COURT: And how are those beyond? Let me
 3 just understand, how are those beyond the contention
 4 interrogatories or is there a problem with documents?

5 MR. MURPHY: Your Honor, we had listed five
 6 categories of information that we were requesting that you
 7 compel Roquette to produce. And I'll try to be brief.

8 THE COURT: Well, did they confirm already that
 9 the protocols and raw data have been produced? Did they
 10 confirm that in their second letter?

11 MR. MURPHY: They have, Your Honor. They con-
 12 firmed that as well back in June and then they supplemented
 13 with additional testing or protocol information and they
 14 told us that was it, they don't have any more. They made a
 15 comprehensive search for that kind of information. And then
 16 just, this month, on Friday, in fact, we received further
 17 supplementation.

18 So we're just concerned that we do not have all
 19 the testing information that we're entitled to. There has
 20 really been very few documents related to specifically the
 21 test methods that the Roquette scientists used to perform
 22 their alleged infringement testing. And they've represented
 23 that we have it all but, twice, we got supplementations.

24 So, again, we first found it hard to believe
 25 that they didn't have this kind of information because what

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1 they provided was really just pages of test results and
 2 there was no support, no raw data, no description of the
 3 test methods used by the scientists and we certainly just
 4 couldn't understand that scientist perform these tests
 5 without documenting what they did. But, Your Honor, we'll
 6 take their representation. If that is all the documents
 7 related to their infringement testing that there are, then
 8 that's all we can do.

9 THE COURT: Doug.

10 MR. RIGLER: We've made three searches and we
 11 have given them everything that we have. It's a responsible
 12 client. It searched responsibly. They may wish that there
 13 were different kinds of data but there isn't.

14 THE COURT: All right.

15 MR. MURPHY: Okay. Your Honor, we'll accept
 16 that.

17 MR. RIGLER: I happen to agree with them that
 18 they're entitled to test data but that has never been an
 19 issue and we have searched and given them what they have. I
 20 disagree with his conclusion as to what the data represents
 21 or shows, but to the extent there is paper out there it's
 22 been produced.

23 THE COURT: All right.

24 MR. MURPHY: The second area of information
 25 we're requesting has to do with identification of products

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1 suit already existed before the patent, the alleged
 2 invention and therefore we can show anticipation. And
 3 that's the straightforward reason why we're asking for an
 4 identification of those products and samples from Roquette.

5 THE COURT: Mr. Rigler? Doug?

6 MR. RIGLER: They're referring to two patents
 7 that date from seven years prior to this, to the application
 8 in 1993 for the '777 patent in suit. They had the patent.
 9 They can compare any disclosures in these patents if they
 10 wanted to use that to invalidate and that's fair game. The
 11 idea that we go out and search for sample products which we
 12 have never said one way or another, that would require us to
 13 speculate as to what products may or may not be covered by
 14 those patents.

15 I haven't told them but I'll reveal now that as
 16 to one of them, we never made any product under the patent.
 17 It's just pointless. They're asking for foreign products of
 18 a patent from a different family seven years prior. It has
 19 nothing to do with this. It would be expensive, it would be
 20 burdensome, it would be speculative. And I don't know of
 21 any legal basis for it.

22 Jeff, do you want to chime in?

23 MR. SNAY: No.

24 THE COURT: Okay.

25 MR. MURPHY: Your Honor, may I respond to that?

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1 and samples covered by certain French patents that are
 2 disclosed in the patent in suit. These French patents have
 3 U.S. counterparts. In the background section of the '777
 4 patent, those French patents are specifically identified
 5 as prior art to the alleged invention in suit. And just
 6 like the patent in suit, those French patents relate to
 7 pulverulent mannitol and the properties of the pulverulent
 8 mannitol claimed in those French patents is measured by the
 9 same tests that are set forth in the Roquette patent in
 10 suit. And in fact during prosecution of the Roquette patent
 11 in suit, the French patents were used by the patent examiner
 12 as bases for rejecting the patent in suit. So, first of
 13 all, they're relevant in that respect. And the reason we're
 14 asking for identification of products and samples, if we can
 15 obtain them from Roquette, is because we like to test those
 16 products.

17 And, Your Honor, there is an old axiom in patent
 18 law that a product that would literally infringe if later in
 19 time anticipates if earlier. So if we receive samples of
 20 these products covered by these prior art French patents, we
 21 test them according to the test methods claimed in claim 1
 22 of Roquette's patent and we find that that mannitol would
 23 infringe Roquette's patent, well, the fact that that
 24 mannitol is produced by prior art methods would show that
 25 in fact the properties claimed in the Roquette patent in

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1 THE COURT: Yes. Yes, you may.

2 MR. MURPHY: We're asking for Roquette to
 3 identify a product under a U.S. patent which is a counter-
 4 part to a French patent. If they have a product that was
 5 marked with the patent numbers, then they obviously believed
 6 that their product was covered by that patent. It seems
 7 like simple information for them to find out whether or not
 8 they're marketing a product that has a patent marking of
 9 that particular patent on the label or on the box. And if
 10 it's available, commercially we'll obtain it. If it's not,
 11 we'd ask a small sample be provided to us.

12 We didn't know one of the French patents has
 13 never had a product that is covered under the patent but
 14 perhaps the other one does. And if we can simply get an
 15 identification of the product name, we'll try to obtain it.
 16 If it's obtainable, we'll get it, but if not, we'd ask
 17 Roquette to provide a sample.

18 THE COURT: The let me ask one question because
 19 I'm ignorant on this point, and that is does French law
 20 require you to mark products with a patent number?

21 MR. MURPHY: Your Honor, actually we've referred
 22 it to as the French patents because that is the way they're
 23 described in the patent disclosure but there are U.S.
 24 counterparts to those French patents.

25 THE COURT: And the counterparts you are talking

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1 about are the '045 and the '046.

2 MR. MURPHY: Yes, Your Honor. And those are
3 Roquette patents. They're not third-party patents, they're
4 Roquette patents.

5 THE COURT: I understand that. Now, Doug,
6 you're saying that they're not of the same family?

7 MR. RIGLER: That's correct.

8 MR. MURPHY: Your Honor, they're prior art
9 patents.

10 THE COURT: But they are prior art patents.

11 MR. RIGLER: Yes, but they are not of the same
12 family.

13 THE COURT: But if they're prior art patents,
14 they're prior art.

15 MR. RIGLER: They were cited as prior art in the
16 application and the references. That is certainly correct.

17 THE COURT: Okay. So there was a recognition on
18 the part of Roquette that they could very well be prior art.

19 MR. RIGLER: Okay.

20 THE COURT: So I think that identifying the
21 products, if there were any, would be the first step.

22 MR. RIGLER: But it's the patents that are prior
23 art, not any products.

24 THE COURT: The products weren't prior art. If
25 they were marked, the products were marked with this patent,

1 for a full and complete detail concerning the facts related
2 to conception or reduction to practice of the alleged
3 invention of the patent in suit. And since early June,
4 we've complained that the response to that interrogatory has
5 been deficient.

6 At our first meet and confer, Roquette agreed to
7 supplement and they did and they merely referenced a range
8 of Bates pages and they contended that those pages provided
9 the requested information. The fact is those pages, many
10 of them are selected pages of laboratory notebooks. For
11 instance, table of contents of laboratory notebooks followed
12 by pages that allegedly show results of this testing or
13 development of their alleged invention. But the fact is
14 that pages we've received are notebooks that are not issued
15 in the names of either of the named inventors on the patent,
16 so those pages don't provide any context as a narrative
17 explanation of the events of conception, reduction to
18 practice would as a response to that interrogatory. We
19 don't think it's that burdensome for them to simply state
20 in narrative fashion what the actual events were for the
21 Roquette inventors, how they invented, conceived the
22 invention and developed it, and we would ask that they
23 supplement their response accordingly.

24 THE COURT: All right. Doug?

25 MR. RIGLER: I don't know how we do that beyond

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1 I don't know which number it is, whether it's the '045 or
2 the '046, then that would be an indication that it was
3 considered by at least Roquette that it was consistent with,
4 it encompassed or the patent involved.

5 MR. RIGLER: Okay.

6 THE COURT: So if there were products that were
7 marked with these patent numbers, the products could be
8 identified.

9 MR. RIGLER: All right. I will see if we have
10 any products that were marked, and if so ...

11 THE COURT: And then we'll deal with the issue
12 later on whether or not, one, if there were no products,
13 then there was no reason to identify.

14 MR. RIGLER: Exactly. Okay. I will undertake
15 to do that promptly.

16 THE COURT: And then we'll possibly have to deal
17 with the other issue later on but I'm not going to deal with
18 it now.

19 Conception and reduction to practice, is that
20 another issue?

21 MR. MURPHY: Yes, Your Honor. That was the
22 third area. Again, we think this is a straightforward
23 request and it's not burdensome for Roquette to supplement
24 its interrogatory response.

25 Back in March, our initial interrogatories asked

1 the documents. I would point out that they have noticed the
2 deposition of both of the inventors and they certainly can
3 develop any narrative from that. This looking looks to me
4 like difficult "make work" for something that happened back
5 in '92 or '93.

6 THE COURT: Let me ask you, though, I think one
7 of the concerns they express; and I may have misunderstood
8 you, Dan; was that you don't have the actual inventor's
9 notebook, you have the notebooks from others.

10 MR. RIGLER: Oh, they have the actual inventor's
11 notebook.

12 THE COURT: They do?

13 MR. RIGLER: I don't know what Dan is referring
14 to. But if we gave them something of someone working for
15 or under the inventor, that would be trying to be fully
16 responsive, but certainly we're not withholding the
17 inventor's notebook on this.

18 MR. MURPHY: Well, yes. We perceive notebooks
19 with, for instance, a general name of a lab, but not -- we
20 can't tell whether it was the inventor's notebook. And then
21 there has been identification of individuals who are unknown
22 to us that are not the inventors. I don't know if that is
23 the technician working under the inventor.

24 MR. RIGLER: That is what you are going to find
25 out during the deposition. To write you an essay on it

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1 strikes me as total "make work." You have the documents
 2 that outline the chronology, you have indicated you have the
 3 names, and you have already noticed the deposition of the
 4 inventors which you are entitled to. So I don't understand
 5 the problem.

6 MR. MURPHY: We don't know who those individuals
 7 are. We'd rather not have to notice people just based on
 8 the names and the documents. If we had received an adequate
 9 response to these interrogatories, we would at least have a
 10 conception of what occurred, what were the important events,
 11 when it happened, who was involved, and we think we are
 12 entitled to that information and don't have to notice
 13 individuals who may not be relevant.

14 MR. RIGLER: But you already have that. That's
 15 why the rule provides that if documents provide the answer,
 16 and I think what you just said reconfirms that you already
 17 have all of that.

18 THE COURT: Well, I think one thing, though, is
 19 this. And I caution both of you on this point. That to the
 20 extent documents are produced and there is a whole list of
 21 names involved, I do think there is an obligation on the
 22 part of counsel to identify who those persons are.

23 MR. RIGLER: We would be glad to do that.

24 THE COURT: And I think you deserve that. But I
 25 also agree that under Rule 33 -- I may be quoting the wrong

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1 privilege and our work product. We've contended the foreign
 2 prosecution files are irrelevant but we, notwithstanding the
 3 objection, we've gone out and given it to them, and then
 4 they came back and they complained you gave us the public
 5 prosecution file. They said, exactly so, you could have
 6 gotten those and we told you that all along, they're public
 7 documents, but I don't think it was even included within
 8 their request. I think if we look at the actual request,
 9 they asked for the prosecution files, the file histories,
 10 but to the extent that Roquette's legal personnel were
 11 talking with their foreign patent attorneys, back and forth,
 12 that obviously is privileged.

13 THE COURT: Well, let me just back up a little
 14 bit. What privilege are you asserting, American or French?

15 MR. RIGLER: I guess I'd assert both. This is
 16 an American proceeding and I believe that Roquette is in
 17 entitled to the protection of attorney-client privilege with
 18 respect to any communications between its attorneys and its
 19 patent attorneys. But I'd also assert it under French, but
 20 I'll have to tell you I'm lesser of my ground there because
 21 I don't know the extent of the French privilege.

22 THE COURT: Well, unfortunately, I'm writing an
 23 opinion on it right now.

24 MR. RIGLER: What is the answer?

25 THE COURT: I haven't got it completed yet but I

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1 rule and maybe it's Rule 34, but one of the rules does
 2 provide that if there is production, that production can
 3 respond to interrogatories.

4 Your problem, Dan, sounds like you don't know
 5 who these people are or how they played into this and
 6 whether they were lab teches or were they lab teches working
 7 under the inventor, that type of thing.

8 MR. MURPHY: That right, Your Honor. We just
 9 don't have any context for.

10 THE COURT: And I think you are entitled to
 11 that. But I also caution, this is a requirement for both
 12 of you. It's not just a requirement for Doug, it's an
 13 obligation for both of you.

14 MR. MURPHY: Yes, Your Honor.

15 THE COURT: It's an obligation that would exist
 16 in responding to discovery in the past and in the future in
 17 this case.

18 Okay.

19 MR. MURPHY: The fourth area of information,
 20 Your Honor, was attorney or agent patent prosecution files
 21 that we requested from Roquette.

22 THE COURT: Okay. The issue that has been
 23 raised in this is privilege. And what privilege are you
 24 asserting, Doug?

25 MR. RIGLER: That would be attorney-client

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1 have a pretty good idea, and I understand the history of
 2 the French patent privilege pretty well right now, between
 3 the patent agents vs. avocats or people that are industrial
 4 property attorneys. That is, it's basically intellectual
 5 property attorneys. And I'm not 100 percent certain whether
 6 they're necessarily all avocats and how it falls so it's an
 7 interesting and very thorny proposition.

8 But when you raise privilege, the concern that I
 9 have is this: I'm assuming that we're talking about foreign
 10 counterparts to the patent in suit and I'm not certain
 11 whether there would have been communication directly with
 12 an American attorney in the process of prosecuting the
 13 patents or prosecuting the foreign counterparts. And if
 14 the involvement was just counsel and/or patent agents, then
 15 I would think that for those communications, French law
 16 would apply. To the extent there were communications with
 17 American counsel for an American patent, then obviously the
 18 attorney-client privilege in the United States would apply.
 19 But I think it's a thornier issue than what is apparent.

20 So I'm not certain, right offhand, whether or
 21 not the correspondence between foreign prosecution attorneys
 22 and their clients in foreign applications are privileged. I
 23 don't understand how they are related to the patent in suit,
 24 how they're relevant in that regard.

25 MR. MURPHY: Well, certainly during prosecution

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1 of those counterpart applications, there may have been
 2 referenced prior art that was not raised during the U.S.
 3 prosecution of the patent in suit. There may have been
 4 claim terms that were construed by those agents that could
 5 have relevance to the patent in suit and construction of the
 6 terms here. So I think there are a number of reasons why.

7 THE COURT: I think, Dan, what I'm hearing is a
 8 stretch to some extent. And I will reserve on this one.
 9 But what did you receive? You received the foreign
 10 prosecution histories; correct?

11 MR. MURPHY: We received a bulk of documents on
 12 Friday. We haven't gone through them all but they appear to
 13 be foreign prosecution, file history.

14 THE COURT: I think you ought to be looking at
 15 those file histories to determine whether we need to dig
 16 into or even consider the correspondence between foreign
 17 prosecuting attorneys and their clients in the foreign
 18 applications, because I'm not certain it's necessarily
 19 relevant.

20 MR. MURPHY: Your Honor, a number, of course, of
 21 foreign languages we need to translate.

22 THE COURT: I know. I just love it. Are they
 23 all in French, hopefully?

24 MR. MURPHY: All different languages, actually,
 25 Your Honor.

1 they won't be related to our obviousness references. So we
 2 think they have the information. We don't see why they
 3 can't produce it to us because it's not a matter of that
 4 they have to tailor that evidence to our particular
 5 references that we might put forward as obviousness
 6 invalidating art.

7 And, furthermore, Your Honor, in their letter
 8 in July, we asked for that information. They agreed to
 9 supplement without qualification. I think it's Exhibit E in
 10 our August 24th letter.

11 THE COURT: Let me look at the August 24th
 12 letter.

13 I see it. It just says we'll produce existing
 14 responsive documents, if any.

15 MR. MURPHY: Now there is a qualification
 16 that we have to put forth basically our obviousness
 17 contentions before they're willing to give us secondary
 18 indicia. They didn't see fit to say that, though, back in
 19 July.

20 THE COURT: All right. Doug.

21 MR. RIGLER: I think this emphasizes again my
 22 concern that I need to voice that they have thrown the book
 23 at the question of obviousness. The patent is presumed
 24 valid. They have to upset it by clear and convincing
 25 evidence. And this again shows that we're still in the

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1 THE COURT: That's nice. I can only help you
 2 with the French privilege. I can't help you with any other
 3 country right now, except for the United States, but I think
 4 that ought to be gone through before we start delving into
 5 foreign prosecution. What foreign prosecuting attorneys are
 6 saying to their client.

7 MR. MURPHY: Yes, Your Honor.

8 Our last category of information was related to
 9 Roquette's secondary indicia evidence of nonobviousness.

10 THE COURT: Don't you have the burden of proof
 11 on obviousness, though?

12 MR. MURPHY: We do, Your Honor.

13 THE COURT: And that isn't a secondary indicia
 14 consideration for saying that the patent is nonobvious
 15 potentially in part based upon what your obviousness
 16 contentions are?

17 MR. MURPHY: It does rebut our obviousness
 18 challenge.

19 THE COURT: Yes.

20 MR. MURPHY: But I don't think it's contingent,
 21 on. The evidence that they're going to present isn't
 22 contingent on the particular reference that we might put
 23 forward or our analysis. I mean whether it's commercial
 24 success information or industry recognition, the secondary
 25 indicia, they already exist. They are not related to or

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1 dark. We're basically being asked to prove our patent is
 2 valid, notwithstanding the statutory command that it's
 3 presumed to be valid.

4 Be that as it may, I think our objection is
 5 extremely well taken that they have to come forward. And
 6 that's what I've been hammering on it all afternoon is I
 7 want to know why they say it's invalid. Notwithstanding, we
 8 did agree we would give it to them because I didn't want to
 9 burden the Court and we have given them what we know and the
 10 reservation that Dan was referring to doesn't mean we're
 11 holding anything back. It means we're still in the dark but
 12 we have nothing more to supplement.

13 This issue really is a moot point right now.
 14 If, and when, I finally get to see why they contend the
 15 patent is invalid, then that may trigger something but as of
 16 right now, we have given them whatever we've been able to
 17 locate.

18 THE COURT: Well, my recollection is that the
 19 secondary considerations for nonobviousness have their nexus
 20 predominantly to show the characteristics of the patent and
 21 the qualities of the patent that support the nonobviousness
 22 defense to obviousness. So how does knowing what the
 23 obviousness contentions are fit into that?

24 MR. RIGLER: I don't know, because I don't know
 25 what their obviousness contention is.

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1 THE COURT: No, no. My understanding is that
 2 the nonobviousness type support is, its nexus comes from the
 3 fact that the secondary considerations all are borne out of
 4 the invention within the patent or inventions within the
 5 patent or what the patent claims provide and how they are
 6 novel and unique in their own way. So explain to me how
 7 those secondary considerations then, since it's directly
 8 related to the patent, you need the obviousness contentions
 9 to be able to answer that. You said to me that you have
 10 answered it as far as you can.

11 MR. RIGLER: Right. If we have secondary
 12 considerations, we've produced documents, such documents as
 13 we have located. We're not holding back right now. What
 14 I'm saying is if you tell us, well, it should have been
 15 obvious by this or that, that may trigger something and
 16 we'll supplement. That's all we're saying.

17 THE COURT: Well, I'm still trying to figure
 18 out how -- and this is an issue -- how knowing what the
 19 obviousness contentions are, specifics regarding those,
 20 necessarily goes to the secondary considerations, if my
 21 assumption is correct that the secondary considerations have
 22 to be a nexus directly related to the patent, not secondary
 23 considerations nexus to obviousness.

24 MR. RIGLER: Okay. But it still comes up in
 25 relation to an attack on the patent. And the patent is

1 THE COURT: Did you guys come to an agreement?
 2 MR. RIGLER: I think so.
 3 MR. MURPHY: I think so, Your Honor.
 4 THE COURT: Okay. Thank you. I just thought I
 5 would let you go for a little bit and see if you could.
 6 Is that it on the issues that were raised by SPI
 7 Pharma, Dan?

8 MR. MURPHY: I'm sorry, Your Honor?
 9 THE COURT: I'm sorry. Is that it on the issues
 10 raised by SPI Pharma?

11 MR. MURPHY: Yes, that is it.
 12 THE COURT: Okay. I look forward, counsel, to
 13 the other information that you will be sending to me, and
 14 we'll see it on September 10th. If, in the interim between
 15 then and now, which I doubt, I can get a teleconference in
 16 with you concerning the motion to dismiss, I will. Doug, I
 17 recognize that you are going to be out of the box for about
 18 two weeks or so. During that time period, if something does
 19 come up, I may then talk with your staff or with other
 20 attorneys that are assigned to the case from your office.

21 MR. RIGLER: That's fine. You can talk to
 22 Andrew Patch, whom you know I think, or Jeff Snay, whom you
 23 don't know but who is with me here and was in the prior
 24 conversation with you as well.

25 THE COURT: All right. Counsel, thank you very

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 1 still presumed valid.

2 THE COURT: Well, the patent is still presumed
 3 valid until somebody tells you that it isn't.

4 MR. RIGLER: Yes, but that's sort of the point.
 5 All I said is it isn't but they haven't told us how or why
 6 it isn't.

7 THE COURT: Give me one.

8 MR. MURPHY: Well, we did, Your Honor. And
 9 you're right, it's objective evidence of nonobviousness.
 10 And it's not tied to the prior art, it's tied to the patent
 11 and the invention. And that evidence exists irrespective of
 12 whatever prior art references we put forward.

13 MR. RIGLER: Well, I sort of disagree and I take
 14 Judge Thynge's point. And it's a very good question. I
 15 guess I just don't understand this discussion right now,
 16 Dan. We don't have anything more we can give you. If we
 17 can find something, we'll give it to you.

18 MR. MURPHY: Okay. I just kept hearing that our
 19 contentions might trigger something. But if you are saying
 20 you don't have any more information?

21 MR. RIGLER: I'm saying we don't have any more
 22 information. I'm saying if we locate any more information,
 23 we'll give it to you. I'm not resisting giving it to you
 24 but, you know, this is a nonexistent issue.

25 MR. MURPHY: That's fine then.

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1 much. Before I close it out, are there any other matters
 2 that counsel wishes to bring up to the Court right now?

3 MR. MURPHY: For SPI, No, Your Honor.

4 MR. RIGLER: Not for Roquette.

5 THE COURT: All right. Thank you, counsel.

6 MR. RIGLER: Thank you for giving us all an
 7 opportunity to go home early by your standards tonight.

8 THE COURT: Let me tell you by, compared to last
 9 night, it's about two hours earlier from when I finally
 10 left.

11 MR. RIGLER: Right.

12 THE COURT: Thank you, all.

13 MR. RIGLER: Thank you very much.

14 MR. MURPHY: Thanks, Your Honor.

15 THE COURT: Good-bye now.

16 (Telephone conference ends at 6:32 p.m.)

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